Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Hyperlipidemia Agents

This criteria was recommended for review by the Vendor Drug Program to ensure appropriate and safe utilization

Clinical Criteria Information Included in this Document

Juxtapid (Lomitapide)

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic**: a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram**: a visual depiction of the clinical criteria logic
- **Supporting tables**: a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References**: clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Praluent (Alirocumab)

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical criteria
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Repatha (Evolocumab)

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Revision Notes

Initial publication and presentation of Juxtapid (lomitapide) clinical criteria to the DUR Board

Juxtapid (Lomitapide)

Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
JUXTAPID 10 MG CAPSULE	33912
JUXTAPID 20 MG CAPSULE	33913
JUXTAPID 30 MG CAPSULE	38574
JUXTAPID 40 MG CAPSULE	38571
JUXTAPID 5 MG CAPSULE	33909
JUXTAPID 60 MG CAPSULE	38573

RxPERT® PAXPRESS™

Juxtapid (Lomitapide)

Clinical Criteria Logic

1. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes (Go to #2)
   [ ] No (Deny)

2. Does the client have a **diagnosis of homozygous familial hypercholesterolemia (HoFH)** in the last 730 days?
   [ ] Yes (Go to #3)
   [ ] No (Deny)

3. Is the client currently pregnant?
   [ ] Yes (Deny)
   [ ] No (Go to #4)

4. Does the client have a claim for a strong or moderate CYP3A4 inhibitor in the last 90 days?
   [ ] Yes (Deny)
   [ ] No (Go to #5)

5. Does the client have a diagnosis of moderate or severe hepatic impairment in the last 365 days?
   [ ] Yes (Deny)
   [ ] No (Go to #6)

6. Does the client have at least one claim for Juxtapid (lomitapide) in the last 90 days?
   [ ] Yes (Go to #7)
   [ ] No (Go to #8)

7. Has the client shown clinical response (significant lowering of LDL-C*) since initiation of Juxtapid (lomitapide) therapy? [MANUAL]
   [ ] Yes (Go to #10)
   [ ] No (Deny)

8. Has the client had at least 90 consecutive days of high dose atorvastatin therapy, 90 consecutive days of high dose rosuvastatin therapy and 90 consecutive days of ezetimibe therapy in the last 730 days?
   [ ] Yes (Go to #9)
   [ ] No (Deny)

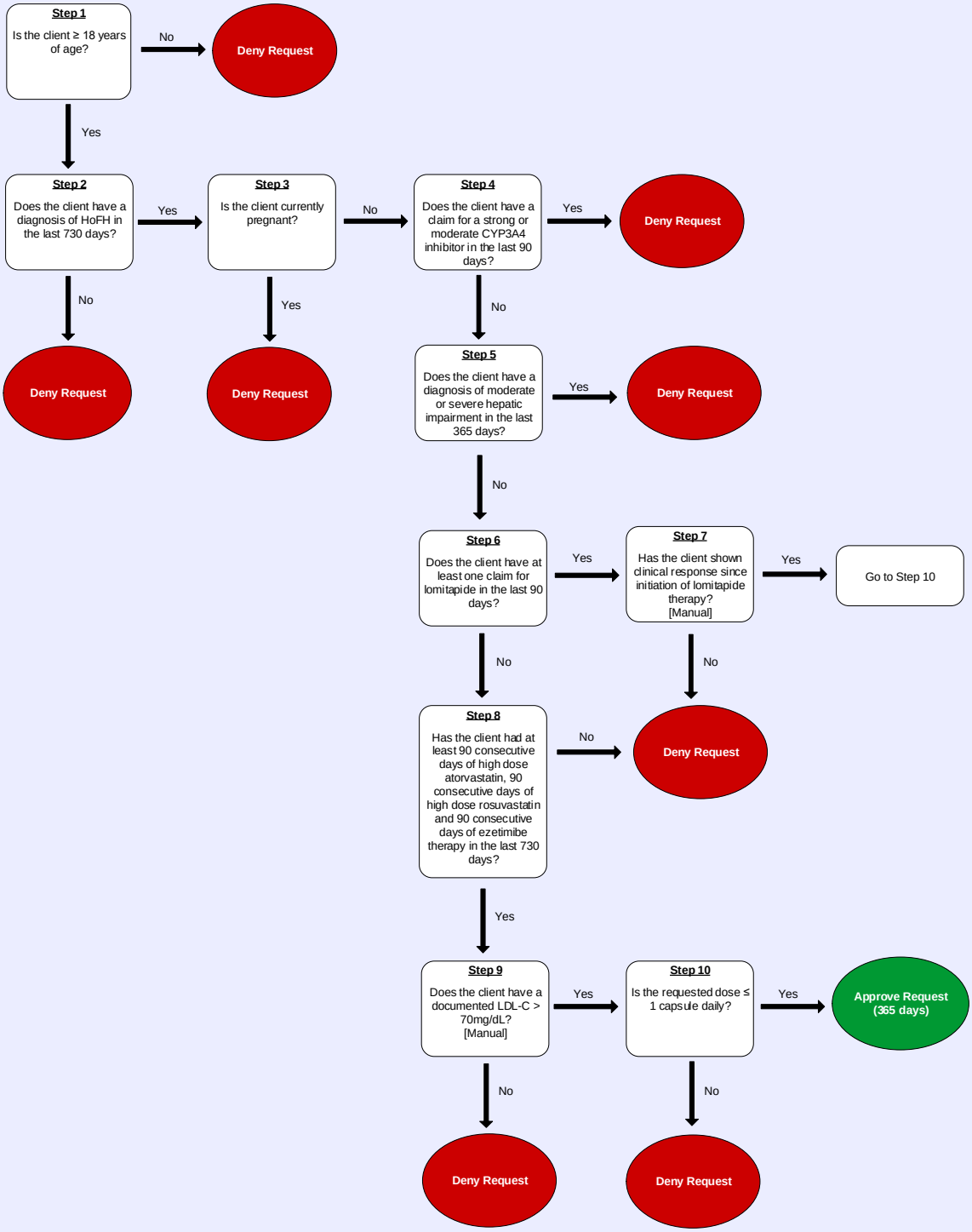
9. Does the client have a documented LDL-C of greater than (>) 70mg/dL? [MANUAL]
   [ ] Yes (Go to #10)
   [ ] No (Deny)

10. Is the requested dose less than or equal to (≤) 1 capsule daily?
    [ ] Yes (Approve – 365 days)
    [ ] No (Deny)

    *Significant lowering of LDL-C is defined as a 30% decrease in LDL for patients with a diagnosis of homozygous familial hypercholesterolemia.

Juxtapid (Lomitapide) Agents

Clinical Criteria Logic Diagram



Juxtapid (Lomitapide) Agents

Clinical Criteria Supporting Tables

Praluent (Alirocumab)

Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
PRALUENT 150MG/ML PEN	39184
PRALUENT 75MG/ML PEN	39182

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Praluent (Alirocumab)

Clinical Criteria Logic

1. Has the provider submitted a PA form for the request?
   [ ] Yes – Go to #2
   [ ] No – Deny

2. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes – Go to #3
   [ ] No – Deny

3. Does the client have a diagnosis of **primary hyperlipidemia** in the last 730 days?
   [ ] Yes – Go to #5
   [ ] No – Go to #4

4. Does the client have a diagnosis of clinical **atherosclerotic cardiovascular disease (ASCVD)** in the last 730 days?
   [ ] Yes – Go to #5
   [ ] No – Deny

5. Does the client have a concurrent claim for **atorvastatin or rosuvastatin**?
   [ ] Yes – Go to #6
   [ ] No – Deny

6. Does the client have 1 claim for **Praluent or Repatha** in the last 90 days?
   [ ] Yes – Go to #7
   [ ] No – Go to #8

7. Has the client shown clinical response (significant lowering of LDL-C*) since initiation of PCSK9 inhibitor therapy? [MANUAL]
   [ ] Yes – Approve (180 days)
   [ ] No – Deny

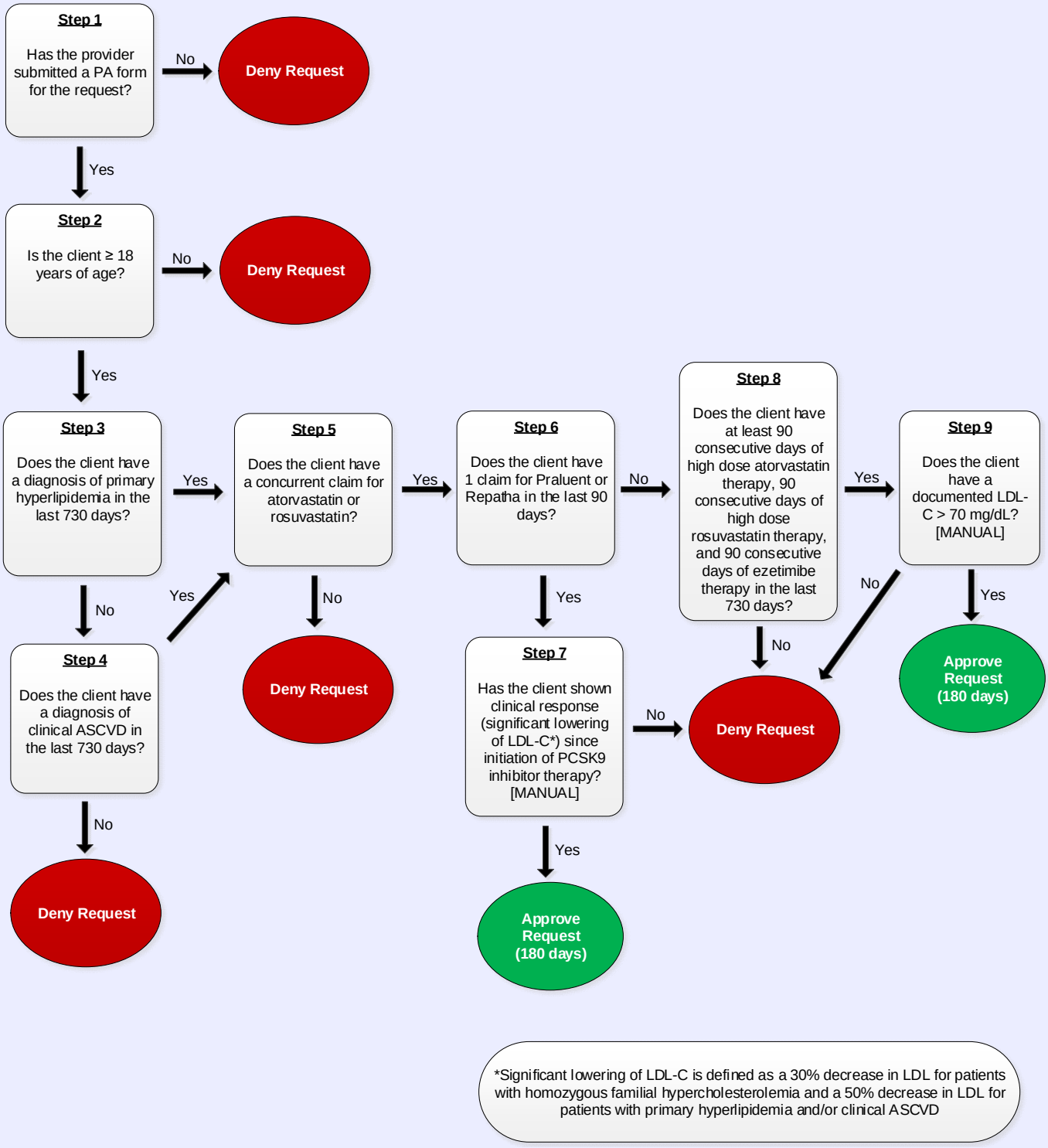
8. Does the client have at least 90 consecutive days of **high dose atorvastatin therapy, 90 consecutive days of high dose rosuvastatin therapy, and 90 consecutive days of ezetimibe therapy** in the last 730 days?
   [ ] Yes – Go to #9
   [ ] No – Deny

9. Does the client have a documented LDL-C of greater than (>) 70mg/dL? [MANUAL]
   [ ] Yes – Approve (180 days)
   [ ] No – Deny

*Significant lowering of LDL-C is defined as a 30% decrease in LDL for patients with a diagnosis of homozygous familial hypercholesterolemia and a 50% decrease in LDL for patients with a diagnosis of primary hyperlipidemia and/or clinical ASCVD.

Praluent (Alirocumab)

Clinical Criteria Logic Diagram



RxPERT PAxpress

Praluent (Alirocumab)

Clinical Criteria Supporting Tables

Step 3 (diagnosis of primary hyperlipidemia) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
E7801	FAMILIAL HYPERCHOLESTEROLEMIA
E782	MIXED HYPERLIPIDEMIA
E785	HYPERLIPIDEMIA, UNSPECIFIED

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
G450	VERTEBRO-BASILAR ARTERY SYNDROME
G451	CAROTID ARTERY SYNDROME (HEMISPHERIC)
G452	MULTIPLE AND BILATERAL PRECEREBRAL ARTERY SYNDROMES
G453	AMAUROSIS FUGAX
G454	TRANSIENT GLOBAL AMNESIA
G458	OTHER TRANSIENT CEREBRAL ISCHEMIC ATTACKS AND RELATED SYNDROMES
G459	TRANSIENT CEREBRAL ISCHEMIC ATTACK, UNSPECIFIED
I200	UNSTABLE ANGINA
I2101	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT MAIN CORONARY ARTERY
I2102	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT ANTERIOR DESCENDING CORONARY ARTERY
I2109	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER CORONARY ARTERY OF ANTERIOR WALL
I2111	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING RIGHT CORONARY ARTERY
I2119	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER CORONARY ARTERY OF INFERIOR WALL
I2121	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT CIRCUMFLEX CORONARY ARTERY
I2129	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER SITES

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
I213	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION OF UNSPECIFIED SITE
I214	NON-ST ELEVATION (NSTEMI) MYOCARDIAL INFARCTION
I240	ACUTE CORONARY THROMBOSIS NOT RESULTING IN MYOCARDIAL INFARCTION
I248	OTHER FORMS OF ACUTE ISCHEMIC HEART DISEASE
I63011	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT VERTEBRAL ARTERY
I63012	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT VERTEBRAL ARTERY
I63019	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED VERTEBRAL ARTERY
I6302	CEREBRAL INFARCTION DUE TO THROMBOSIS OF BASILAR ARTERY
I63031	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT CAROTID ARTERY
I63032	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT CAROTID ARTERY
I63039	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED CAROTID ARTERY
I6309	CEREBRAL INFARCTION DUE TO THROMBOSIS OF OTHER PRECEREBRAL ARTERY
I6310	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED PRECEREBRAL ARTERY
I63111	CEREBRAL INFARCTION DUE TO EMBOLISM OF RIGHT VERTEBRAL ARTERY
I63112	CEREBRAL INFARCTION DUE TO EMBOLISM OF LEFT VERTEBRAL ARTERY
I63119	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED VERTEBRAL ARTERY
I6320	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED PRECEREBRAL ARTERIES
I63211	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT VERTEBRAL ARTERIES
I63212	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT VERTEBRAL ARTERIES
I63219	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED VERTEBRAL ARTERIES
I6322	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF BASILAR ARTERIES
I63231	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT CAROTID ARTERIES
I63232	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT CAROTID ARTERIES

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
I63239	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED CAROTID ARTERIES
I6329	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF OTHER PRECEREBRAL ARTERIES
I6330	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED CEREBRAL ARTERY
I63311	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT MIDDLE CEREBRAL ARTERY
I63312	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT MIDDLE CEREBRAL ARTERY
I63319	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED MIDDLE CEREBRAL ARTERY
I63321	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT ANTERIOR CEREBRAL ARTERY
I63322	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT ANTERIOR CEREBRAL ARTERY
I63329	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED ANTERIOR CEREBRAL ARTERY
I63331	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT POSTERIOR CEREBRAL ARTERY
I63332	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT POSTERIOR CEREBRAL ARTERY
I63339	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED POSTERIOR CEREBRAL ARTERY
I63341	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT CEREBELLAR ARTERY
I63342	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT CEREBELLAR ARTERY
I63349	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED CEREBELLAR ARTERY
I6339	CEREBRAL INFARCTION DUE TO THROMBOSIS OF OTHER CEREBRAL ARTERY
I6340	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED CEREBRAL ARTERY
I63411	CEREBRAL INFARCTION DUE TO EMBOLISM OF RIGHT MIDDLE CEREBRAL ARTERY
I63412	CEREBRAL INFARCTION DUE TO EMBOLISM OF LEFT MIDDLE CEREBRAL ARTERY
I63419	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED MIDDLE CEREBRAL ARTERY
I63421	CEREBRAL INFARCTION DUE TO EMBOLISM OF RIGHT ANTERIOR CEREBRAL ARTERY
I63422	CEREBRAL INFARCTION DUE TO EMBOLISM OF LEFT ANTERIOR CEREBRAL ARTERY

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
I63429	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED ANTERIOR CEREBRAL ARTERY
I63431	CEREBRAL INFARCTION DUE TO EMBOLISM OF RIGHT POSTERIOR CEREBRAL ARTERY
I63432	CEREBRAL INFARCTION DUE TO EMBOLISM OF LEFT POSTERIOR CEREBRAL ARTERY
I63439	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED POSTERIOR CEREBRAL ARTERY
I63441	CEREBRAL INFARCTION DUE TO EMBOLISM OF RIGHT CEREBELLAR ARTERY
I63442	CEREBRAL INFARCTION DUE TO EMBOLISM OF LEFT CEREBELLAR ARTERY
I63449	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED CEREBELLAR ARTERY
I6349	CEREBRAL INFARCTION DUE TO EMBOLISM OF OTHER CEREBRAL ARTERY
I6350	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED CEREBRAL ARTERY
I63511	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT MIDDLE CEREBRAL ARTERY
I63512	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT MIDDLE CEREBRAL ARTERY
I63519	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED MIDDLE CEREBRAL ARTERY
I63521	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT ANTERIOR CEREBRAL ARTERY
I63522	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT ANTERIOR CEREBRAL ARTERY
I63529	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED ANTERIOR CEREBRAL ARTERY
I63531	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT POSTERIOR CEREBRAL ARTERY
I63532	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT POSTERIOR CEREBRAL ARTERY
I63539	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED POSTERIOR CEREBRAL ARTERY
I63541	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT CEREBELLAR ARTERY
I63542	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT CEREBELLAR ARTERY
I63549	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED CEREBELLAR ARTERY
I6359	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF OTHER CEREBRAL ARTERY

Step 4 (diagnosis of ASCVD) Required quantity: *1* Look back timeframe: *730 days*	
ICD-10 Code	**Description**
I636	CEREBRAL INFARCTION DUE TO CEREBRAL VENOUS THROMBOSIS, NONPYOGENIC
I638	OTHER CEREBRAL INFARCTION
I639	CEREBRAL INFARCTION, UNSPECIFIED
I658	OCCLUSION AND STENOSIS OF OTHER PRECEREBRAL ARTERIES
I659	OCCLUSION AND STENOSIS OF UNSPECIFIED PRECEREBRAL ARTERY
I6609	OCCLUSION AND STENOSIS OF UNSPECIFIED MIDDLE CEREBRAL ARTERY
I6619	OCCLUSION AND STENOSIS OF UNSPECIFIED ANTERIOR CEREBRAL ARTERY
I6629	OCCLUSION AND STENOSIS OF UNSPECIFIED POSTERIOR CEREBRAL ARTERY
I669	OCCLUSION AND STENOSIS OF UNSPECIFIED CEREBRAL ARTERY
I672	CEREBRAL ATHEROSCLEROSIS
I6781	ACUTE CEREBROVASCULAR INSUFFICIENCY
I6782	CEREBRAL ISCHEMIA
I6789	OTHER CEREBROVASCULAR DISEASE
I67848	OTHER CEREBROVASCULAR VASOSPASM AND VASOCONSTRICTION
I70201	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, RIGHT LEG
I70202	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, LEFT LEG
I70203	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, BILATERAL LEGS
I70208	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, OTHER EXTREMITY
I70209	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, UNSPECIFIED EXTREMITY
I70211	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, RIGHT LEG
I70212	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, LEFT LEG
I70213	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, BILATERAL LEGS
I70218	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, OTHER EXTREMITY
I70219	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, UNSPECIFIED EXTREMITY
I70221	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, RIGHT LEG
I70222	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, LEFT LEG

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
I70223	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, BILATERAL LEGS
I70228	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, OTHER EXTREMITY
I70229	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, UNSPECIFIED EXTREMITY
I70231	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF THIGH
I70232	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF CALF
I70233	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF ANKLE
I70234	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF HEEL AND MIDFOOT
I70235	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF OTHER PART OF FOOT
I70238	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF OTHER PART OF LOWER RIGHT LEG
I70239	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF UNSPECIFIED SITE
I70241	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF THIGH
I70242	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF CALF
I70243	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF ANKLE
I70244	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF HEEL AND MIDFOOT
I70245	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF OTHER PART OF FOOT
I70248	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF OTHER PART OF LOWER LEFT LEG
I70249	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF UNSPECIFIED SITE
I7025	ATHEROSCLEROSIS OF NATIVE ARTERIES OF OTHER EXTREMITIES WITH ULCERATION
I70261	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, RIGHT LEG
I70262	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, LEFT LEG
I70263	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, BILATERAL LEGS
I70268	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, OTHER EXTREMITY

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
I70269	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, UNSPECIFIED EXTREMITY
I70291	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, RIGHT LEG
I70292	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, LEFT LEG
I70293	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, BILATERAL LEGS
I70298	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, OTHER EXTREMITY
I70299	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, UNSPECIFIED EXTREMITY

Step 5 (concurrent claim for atorvastatin or rosuvastatin) **Required quantity:** *1* **Look back timeframe:** *90 days*	
Description	**GCN**
AMLODIPINE-ATORVAST 10-10 MG	21395
AMLODIPINE-ATORVAST 10-20 MG	21396
AMLODIPINE-ATORVAST 10-40 MG	21397
AMLODIPINE-ATORVAST 10-80 MG	21398
AMLODIPINE-ATORVAST 2.5-10 MG	23866
AMLODIPINE-ATORVAST 2.5-20 MG	23867
AMLODIPINE-ATORVAST 2.5-40 MG	23868
AMLODIPINE-ATORVAST 5-10 MG	21391
AMLODIPINE-ATORVAST 5-20 MG	21392
AMLODIPINE-ATORVAST 5-40 MG	21393
AMLODIPINE-ATORVAST 5-80 MG	21394
ATORVASTATIN 10MG TABLET	43720
ATORVASTATIN 20MG TABLET	73721
ATORVASTATIN 40MG TABLET	43722
ATORVASTATIN 80MG TABLET	43723
CADUET 10-10MG TABLET	21395
CADUET 10-20MG TABLET	21396
CADUET 10-40MG TABLET	21397
CADUET 10-80MG TABLET	21398
CADUET 5-10MG TABLET	21391

Step 5 (concurrent claim for atorvastatin or rosuvastatin) **Required quantity:** *1* **Look back timeframe:** *90 days*	
Description	**GCN**
CADUET 5-20MG TABLET	21392
CADUET 5-40MG TABLET	21393
CADUET 5-80MG TABLET	21394
CRESTOR 10MG TABLET	19153
CRESTOR 20MG TABLET	19154
CRESTOR 40MG TABLET	19155
CRESTOR 5MG TABLET	20229
EZALLOR SPRINKLE 10MG CAPSULE	39996
EZALLOR SPRINKLE 20MG CAPSULE	40734
EZALLOR SPRINKLE 40MG CAPSULE	41027
EZALLOR SPRINKLE 5MG CAPSULE	38314
LIPITOR 10MG TABLET	43720
LIPITOR 20MG TABLET	43721
LIPITOR 40MG TABLET	43722
LIPITOR 80MG TABLET	43723
ROSUVASTATIN 10MG TABLET	19153
ROSUVASTATIN 20MG TABLET	19154
ROSUVASTATIN 40MG TABLET	19155
ROSUVASTATIN 5MG TABLET	20229

Step 6 (Praluent or Repatha therapy) **Required quantity:** *1* **Look back timeframe:** *90 days*	
Description	**GCN**
PRALUENT 150MG/ML PEN	39184
PRALUENT 75MG/ML PEN	39182
REPATHA 140MG/ML SURECLICK	38178
REPATHA 140MG/ML SYRINGE	39363
REPATHA 420MG/3.5ML PUSHTRONX	41834

Step 8 (high dose statin therapy and ezetimibe therapy) **Required quantity:** *90 days* **Look back timeframe:** *120 days*	
Description	**GCN**
ATORVASTATIN 40MG TABLET	43722
ATORVASTATIN 80MG TABLET	43723
CRESTOR 20MG TABLET	19154
CRESTOR 40MG TABLET	19155
EZALLOR SPRINKLE 20MG CAPSULE	40734
EZALLOR SPRINKLE 40MG CAPSULE	41027
EZETIMIBE 10MG TABLET	18387
LIPITOR 40MG TABLET	43722
LIPITOR 80MG TABLET	43723
ROSUVASTATIN 20MG TABLET	19154
ROSUVASTATIN 40MG TABLET	19155
ZETIA 10MG TABLET	18387

Repatha (Evolocumab)

Drugs Requiring Prior Authorization

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Drugs Requiring Prior Authorization	
Label Name	**GCN**
REPATHA 140MG/ML SURECLICK	38178
REPATHA 140MG/ML SYRINGE	39363
REPATHA 420MG/3.5ML PUSHTRONX	41834

RxPERT® PAXPRESS™

Repatha (Evolocumab)

Clinical Criteria Logic

1. Has the provider submitted a PA form for the request?
   [ ] Yes – Go to #2
   [ ] No – Deny

2. Is the client greater than or equal to (≥) 13 years of age?
   [ ] Yes – Go to #3
   [ ] No – Deny

3. Does the client have a diagnosis of homozygous familial hypercholesterolemia in the last 730 days? [MANUAL]
   [ ] Yes – Go to #4
   [ ] No – Go to #5

4. Is the prescribed dose equal to 420mg monthly?
   [ ] Yes – Go to #10
   [ ] No – Deny

5. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes – Go to #6
   [ ] No – Deny

6. Does the client have a diagnosis of **primary hyperlipidemia** in the last 730 days?
   [ ] Yes – Go to #8
   [ ] No – Go to #7

7. Does the client have a diagnosis clinical **atherosclerotic cardiovascular disease (ASCVD)** in the last 730 days?
   [ ] Yes – Go to #8
   [ ] No – Deny

8. Is the prescribed dose equal to 140mg every 2 weeks?
   [ ] Yes – Go to #10
   [ ] No – Go to #9

9. Is the prescribed dose equal to 420mg every 4 weeks?
   [ ] Yes – Go to #10
   [ ] No – Deny

10. Does the client have a concurrent claim for **atorvastatin or rosuvastatin**?
    [ ] Yes – Go to #11
    [ ] No – Deny

11. Does the client have 1 claim for **Repatha or Praluent** in the last 90 days?
    [ ] Yes – Go to #12
    [ ] No – Go to #13

12. Has the client shown clinical response (significant lowering of LDL-C*) since initiation of PCSK9 inhibitor therapy? [MANUAL]
    [ ] Yes – Approve (180 days)
    [ ] No – Deny

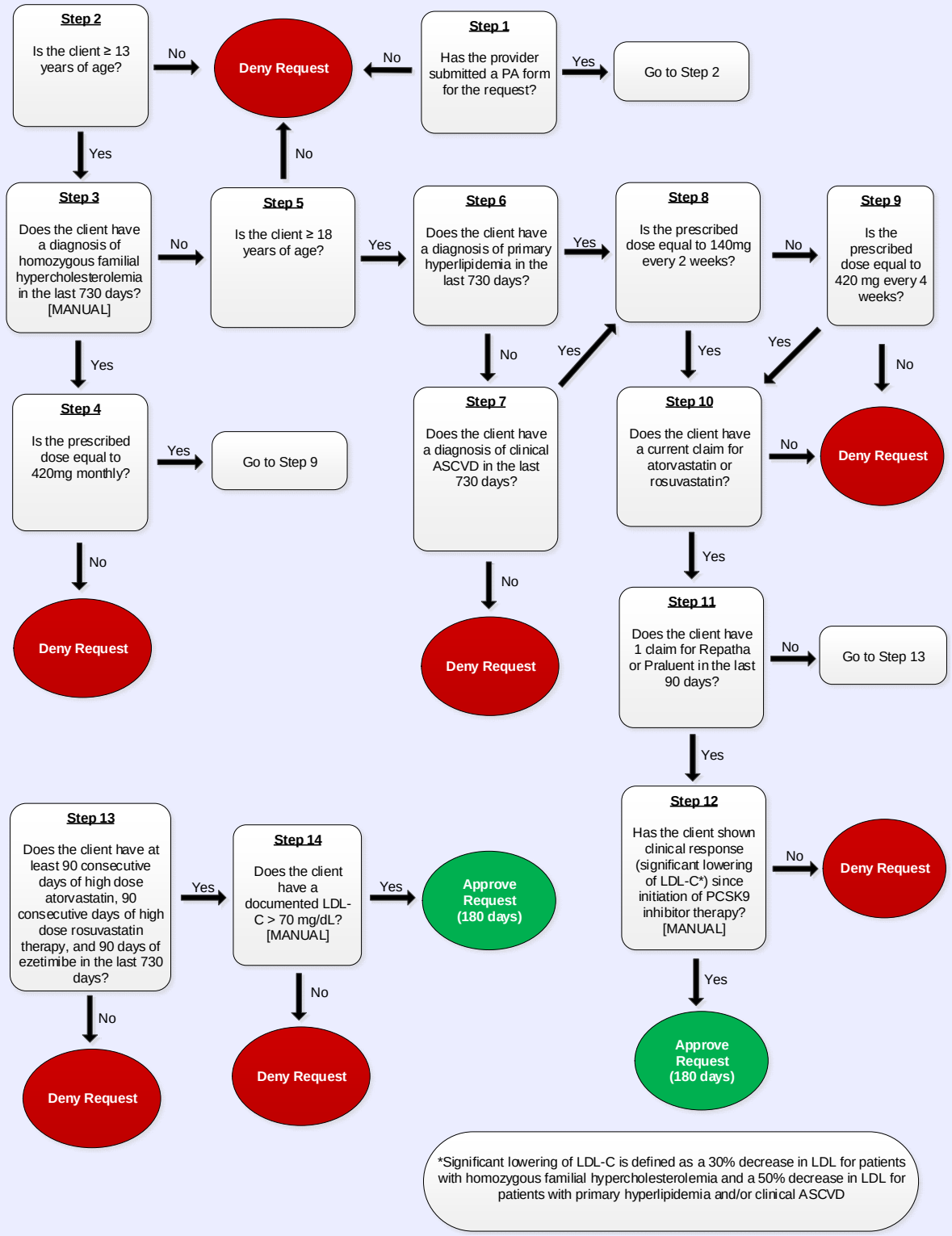
13. Does the client have at least 90 consecutive days of **high dose atorvastatin therapy, 90 consecutive days of high dose rosuvastatin, and 90 consecutive days of ezetimibe therapy** in the last 730 days?
    [ ] Yes – Go to #14
    [ ] No – Deny

14. Does the client have a documented LDL-C of greater than (>) 70mg/dL? [MANUAL]
    [ ] Yes – Approve (180 days)
    [ ] No – Deny

*Significant lowering of LDL-C is defined as a 30% decrease in LDL for patients with a diagnosis of homozygous familial hypercholesterolemia and a 50% decrease in LDL for patients with a diagnosis of primary hyperlipidemia and/or clinical ASCVD.

Repatha (Evolocumab)

Clinical Criteria Logic Diagram



RxPERT PAxpress

Repatha (Evolocumab)

Clinical Criteria Supporting Tables

Step 6 (diagnosis of primary hyperlipidemia)
Required quantity: *1*
Look back timeframe: *730 days*

For the list of diagnosis codes that pertain to this step, see the **Primary Hyperlipidemia** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 7 (diagnosis of ASCVD)
Required quantity: *1*
Look back timeframe: *180 days*

For the list of diagnosis codes that pertain to this step, see the **ASCVD** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 10 (concurrent claim for atorvastatin or rosuvastatin)
Required quantity: *1*
Look back timeframe: *90 days*

For the list of GCNs that pertain to this step, see the **Atorvastatin / Rosuvastatin** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 11 (claim for Praluent or Repatha)
Required quantity: *1*
Look back timeframe: *90 days*

For the list of GCNs that pertain to this step, see the **Praluent / Repatha** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 13 (high dose statin therapy)
Required quantity: *90 days*
Look back timeframe: *730 days*

For the list of GCNs that pertain to this step, see the **High Dose Statin Therapy** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

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Hyperlipidemia Agents

Clinical Criteria References

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5. Repatha Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2019.

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13. Juxtapid Prescribing Information. Dublin, Ireland. Amryt Pharmaceuticals DAC. September 2020.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
10/22/2015	Presented to the DUR Board
11/17/2016	• Updated Criteria Logic • Updated Logic Diagram • Updated Table 4 • Updated Table 5 • Added Table 6 • Added GCN for Repatha 420mg/3.5mL Pushtronx to "Drugs Requiring PA" • Updated Criteria Logic • Updated Logic Diagram • Updated Table 10 • Added Table 11 • Updated References
03/29/2019	• Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.) on each 'Drug Requiring PA' table
04/06/2020	• Annual review by staff • Updated question 3 to 'diagnosis of primary hyperlipidemia' and the LDL requirement on question 9 to ≥ 70mg/dL on criteria logic and logic diagram • Updated question 6 to 'diagnosis of primary hyperlipidemia' and the LDL requirement on question 14 to ≥ 70mg/dL on criteria logic and logic diagram • Updated Table 5 • Updated references
04/23/2021	• Initial publication and presentation of Juxtapid (lomitapide) clinical criteria to the DUR Board